



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0276]

Guidance for Industry: Enforcement Policy Concerning Rotational Warning Plans for Smokeless Tobacco Products; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a guidance entitled “Enforcement Policy Concerning Rotational Warning Plans for Smokeless Tobacco Products,” that was announced in the Federal Register on June 8, 2010.

DATES: The withdrawal is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER.]

FOR FURTHER INFORMATION CONTACT:

Ele Ibarra-Pratt,
Center for Tobacco Products,
Office of Compliance and Enforcement,
Food and Drug Administration,
9200 Corporate Blvd.,
Rockville, MD 20850-3229,
1-877-287-1373,
CTPCompliance@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Public Law 111-31) (Tobacco Control Act) into law. Section 204 of the Tobacco Control Act amended section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (Smokeless Tobacco Act), 15 U.S.C. 4402, to prescribe revised requirements for health warning statements that must appear on smokeless tobacco product packages and advertisements, and to require the submission of warning plans for smokeless tobacco product packages and advertisements to FDA for review and approval, rather than to the Federal Trade Commission (FTC). Section 3(b)(3) of the Smokeless Tobacco Act requires the equal distribution and display of warning statements on packaging, and the quarterly rotation of warning statements in advertising, for each brand of smokeless tobacco product “in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer” to, and approved by, FDA. These requirements took effect on June 22, 2010.

In a notice published in the Federal Register of June 8, 2010 (75 FR 32481), FDA announced the availability of a guidance entitled “Enforcement Policy Concerning Rotational Warning Plans for Smokeless Tobacco Products.” This guidance provided information to industry and the public, including that “[a]t this time, as an exercise of enforcement discretion, FDA does not intend to commence or recommend enforcement of the requirement that a smokeless tobacco manufacturer, distributor, importer, or retailer must have an FDA-approved rotational warning plan, so long as a rotational warning plan has been submitted to FDA by July 22, 2010.” FDA believed that allowing additional time for the review of warning plans would permit an orderly transition of regulatory authority from the FTC to FDA to review and approve warning plans.

FDA is withdrawing this guidance because it is no longer warranted. FDA has completed its review of all of the warning plans for smokeless tobacco products that were submitted to FDA by July 22, 2010, and the transition from FTC to FDA of the responsibility for reviewing warning plans for smokeless tobacco products has been accomplished. Further, this guidance included an incomplete definition of smokeless tobacco. Section 101(c) of the Tobacco Control Act amended the Smokeless Tobacco Act to give smokeless tobacco the meaning that term is given by section 900(18) of the Federal Food, Drug, and Cosmetic Act. Under this definition, “smokeless tobacco” means any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity. (Emphasis added) Thus, withdrawal of this guidance on enforcement policy will also help to prevent any confusion that may have been created by the misstatement of this definition.

For information regarding the submission of warning plans for smokeless tobacco products, you may contact the Office of Compliance at FDA’s Center for Tobacco Products (see FOR FURTHER INFORMATION CONTACT).

We note that FDA has made available for public comment a draft guidance that, when finalized, will represent the Agency’s current thinking on the “Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products.” You can obtain an electronic version of this draft guidance document at either <http://www.regulations.gov/> or <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>.

You can comment on this or any other guidance at any time.

Dated: November 21, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-28809 Filed 11/27/2012 at 8:45 am; Publication Date: 11/28/2012]